IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, ALEMBIC PHARMACEUTICALS, INC., CRYSTAL PHARMACEUTICAL (SUZHOU) CO., LTD., MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, MSN LIFE SCIENCES PRIVATE LIMITED, MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, VIATRIS INC., NANJING NORATECH PHARMACEUTICAL CO., LIMITED, Defendants.	Civil Action No. 22-1395-RGA

MEMORANDUM OPINION

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September 29, 2023

ANDREWS, U.S. DISTRICT JUDGE:

Before me are the motion to dismiss for failure to state a claim filed by Defendant Nanjing Noratech Pharmaceutical Co., Limited ("Noratech") and the motion for judgment on the pleadings filed by Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and MSN Life Sciences Private Limited (collectively "MSN"). (D.I. 26; D.I. 65). I have considered the parties' briefing for both motions. (D.I. 27, 37, 44 (Noratech's motion); D.I. 66, 70, 79 (MSN's motion)). For the reasons set forth below, both motions are DENIED.

The briefings for these motions raise several similar arguments. For convenience, I will consider them together.

I. BACKGROUND

This dispute is part of a group of patent infringement actions related to Novartis's Entresto product and associated Novartis-owned patents. (D.I. 1, ¶1; D.I. 70 at 1–5). These patents include U.S. Patent No. 8,8767,938 (the "'938 patent"), U.S. Patent No. 9,388,134 (the "'134 patent"), and U.S. Patent No. 11,096,918 (the "'918 patent"). (D.I. 70 at 1–5). The '918 patent is not listed in the FDA's Orange Book. (D.I. 37 at 5).

In October 2019, Novartis filed several actions against MSN, Noratech, and other defendants alleging that each defendant's respective ANDA products infringed various patents, including the '938 patent and the '134 patent. (*Id.* at 2). These actions were later consolidated into multidistrict litigation No. 20-2930. *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, MDL No. 20-2930-RGA, D.I. 1 (D. Del. Mar. 27, 2020). As part of the litigation, Noratech and MSN provided Novartis with their entire ANDAs, samples of their ANDA products and APIs, and other internal documents. (D.I. 37 at 3; D.I. 70 at 2). These documents and materials were subject to a protective order that designated all "technical information relating to the products at

issue" as Highly Confidential. (MDL No. 20-2930-RGA, D.I. 80, ¶¶10, 15). The protective order further provides, "Protected Information will be used solely for the purpose of asserting, maintaining, monitoring, supervising, prosecuting, defending, or settling any claim in these Actions." (*Id.* ¶15). Novartis has since withdrawn its '938 and '134 patent infringement claims against both Noratech and MSN. (D.I. 37 at 3; D.I. 70 at 2).

On September 20, 2021, Novartis filed the 21-1330 suit against seven "defendant groups" who were a part of the MDL litigation on "information and belief" that their respective ANDA products—the same ones challenged in the MDL litigation would infringe the '918 patent. (D.I. 37 at 5; D.I. 70 at 3; *Novartis Pharms. Corp. v. Alkem Lab'ys Ltd.*, C.A. No. 21-1330-RGA (D. Del. September 20, 2021)). This group of defendants did not include Noratech or MSN. During a scheduling conference on August 3, 2022, I ruled that the MDL protective order prevented Novartis from using information produced during the MDL case to initiate other cases involving the same ANDAs. (D.I. 38, Ex. A at 15–17).

On October 24, 2022, Novartis filed the present suit against more defendant groups from the MDL litigation, including Noratech and MSN, again alleging on "information and belief" that the same ANDA products challenged in the MDL litigation will infringe the '918 patent. (D.I. 1, ¶¶131–38, 147–54). Noratech moves to dismiss Novartis's patent infringement claim for failure to state a claim because Novartis's pleadings are inadequate as a matter of law. (D.I. 27 at 2). MSN moves for judgment on the pleadings on the basis that its ANDA products do not infringe the '918 patent as a matter of law. (D.I. 66 at 3).

II. LEGAL STANDARD

A. Motion to Dismiss

Rule 8 requires a complainant to provide "a short and plain statement of the claim showing that the pleader is entitled to relief." FED. R. CIV. P. 8(a)(2). Rule 12(b)(6) allows the accused party to bring a motion to dismiss the claim for failing to meet this standard. A Rule 12(b)(6) motion may be granted only if, accepting the well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the complainant, a court concludes that those allegations "could not raise a claim of entitlement to relief." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 558 (2007).

The factual allegations do not have to be detailed, but they must provide more than labels, conclusions, or a "formulaic recitation" of the claim elements. *Id.* at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level . . . on the assumption that all the allegations in the complaint are true (even if doubtful in fact)."). Moreover, there must be sufficient factual matter to state a facially plausible claim to relief. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The facial plausibility standard is satisfied when the complaint's factual content "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* ("Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." (internal quotation marks omitted)).

Courts have recognized a relaxed standard of pleading in situations where "essential information lies uniquely within another party's control." *Exergen Corp. v. Wal–Mart Stores, Inc.*, 575 F.3d 1312, 1330–31 (Fed. Cir. 2009); *McDermott v. Clondalkin Grp., Inc.*, 649 F. App'x 263, 267–68 (3d Cir. 2016); *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410,

1418 (3d Cir.1997). Even under this relaxed standard, "boilerplate and conclusory allegations will not suffice," and plaintiffs have an obligation to "accompany their legal theory with factual allegations that make their theoretically viable claim plausible." *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d at 1418. This Court has similarly recognized a Hatch-Waxman plaintiff could plead with a lower level of specificity than required in other infringement suits and still comply with the *Twombly* and *Iqbal* pleading requirements. *See Belcher Pharms., LLC v. Int'l Medication Sys., Ltd.*, 379 F. Supp. 3d 326, 331–32 (D. Del. 2019).[1]

B. Motion for Judgment on the Pleadings

A Rule 12(c) motion for judgment on the pleadings is reviewed under the same standard as a Rule 12(b)(6) motion to dismiss when the Rule 12(c) motion alleges that the plaintiff failed to state a claim upon which relief can be granted. *See Turbe v. Gov't of the Virgin Islands*, 938 F.2d 427, 428 (3d Cir. 1991); *Revell v. Port Auth.*, 598 F.3d 128, 134 (3d Cir. 2010). The court must accept the factual allegations in the complaint and take them in the light most favorable to the non-moving party. *See Erickson v. Pardus*, 551 U.S. 89, 94 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). "When there are well-ple[d] factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679. The court must "draw on its judicial experience and common sense" to make the determination. *See id.*

"In deciding a Rule 12(c) motion, the court does not consider matters outside the pleadings." *Mele v. Fed. Rsrv. Bank of New York*, 359 F.3d 251, 257 (3d Cir. 2004). "[A] court may consider extraneous documents if the complaint references the documents or if the

[1] As noted, the '918 patent is not in the Orange Book. Thus, the instant case is not on all-fours with *Belcher*.

documents are integral to the plaintiff's claims." *AstraZeneca Pharm. LP v. Apotex Corp.*, 2010 WL 5376310, at *9 (D. Del. Dec. 22, 2010) (citing *In re Burlington*, 114 F.3d at 1426).

III. DISCUSSION

A. Sufficiency of Novartis's pleadings

Noratech and MSN argue that Novartis's "information and belief" pleading does not satisfy the *Twombly* and *Iqbal* pleading requirements. (D.I. 27 at 7–9; D.I. 66 at 8–11). For the following reasons, I find Novartis's pleadings sufficient to survive a Rule 12 motion.

1. The MDL protective order

Noratech and MSN both maintain that Novartis is required to plead with more specificity based on testing data and other documents it obtained during the MDL litigation. (D.I. 27 at 7–9; D.I. 66 at 8; D.I. 79 at 2–4). This argument relies on the premise that the MDL protective order permits Novartis to use technical information, which the order designated "Highly Confidential," to initiate the present action. I have previously interpreted the order as preventing the use of such information in initiating other suits. (D.I. 38, Ex. A. at 15–17). I decline to change my interpretation here and agree with Novartis that it is prohibited from pleading the present action based on testing results and other documents obtained during the MDL litigation.[2]

Both Noratech and MSN point out that Novartis never raised any protective order-related issues to them before or after filing the instant action. (D.I. 44 at 5–6; D.I. 79 at 4). I see no such requirement in the protective order and neither defendant points to any other authority.

[2] Noratech alternatively argues that Novartis violated the MDL protective order by testing, after the filing of its complaint, samples obtained during the prior litigation. (D.I. 44 at 6). Noratech's argument is irrelevant to the question at issue in Noratech's motion to dismiss—whether Novartis's complaint fails to state a claim. I therefore decline to address the issue of whether Novartis's preliminary testing violated the MDL's protective order unless and until the issue is raised in a procedurally appropriate manner.

2. Application of a relaxed pleading standard

Noratech and MSN argue that Novartis's pleading on "information and belief" is inadequate, citing to non-ANDA infringement cases that find such pleading insufficient to survive a Rule 12 motion. (D.I. 27 at 6–9; D.I. 44 at 2–3; D.I. 66 at 8–10). Novartis asserts that it satisfies the *Twombly* and *Iqbal* requirements under the relaxed pleading standard dictated by *Belcher*. (D.I. 37 at 9–12; D.I. 44 at 2–5). I find a relaxed pleading standard appropriate to this context and that Novartis has sufficiently plead its claims.

In *Belcher*, the Court provides a list of reasons Hatch-Waxman plaintiffs are held to a lower level of specificity than plaintiffs in other infringement suits. Among them:

> Plaintiff may not know much about the details of a proposed product and may, again, not be able to plead infringement with specificity. Nor, of course, may the plaintiff go out and purchase the accused product and test it for itself since, in these cases, the product does not yet actually exist (and if samples have been created, they cannot, by law, be available for purchase).

Belcher, 379 F. Supp. 3d at 331–32. It seems to me that *Belcher*'s rationale largely applies to ANDA infringement cases that do not involve an Orange Book patent; owners of such patents still face the same difficulties in retrieving information about the accused products at the pleading stage. These hurdles are notably not present in other infringement cases, such as those cited by Noratech and MSN. *See, e.g.*, *Network Managing Sols., LLC v. AT&T Inc.*, 2017 WL 472080, at *1 (D. Del. Feb. 3, 2017) (alleging on information and belief that plaintiff's patents were infringed by defendants' adoption of publicly available mobile broadband standards); *Artrip v. Ball*, 735 F. App'x 708, 714–15 (Fed. Cir. 2018) (finding information and belief pleading insufficient where plaintiff's attorney had received access to the factory and the products before the complaint was filed); *Blue Spike LLC v. Comcast Cable Comm'ns, LLC*, 2019 WL 4242930, at *3 (D. Del. Sept. 6, 2019) (alleging defendant's commercially available

TV Boxes infringed plaintiff's patents on information and belief); *North Star Innovations, Inc. v. Micron Tech., Inc.*, 2017 WL 5501489, at *2 (finding plaintiff failed to plead sufficient facts to bring a direct infringement claim against defendant's commercially available SDRAM device); *Philips v. ASUSTeK Comput. Inc.*, 2016 WL 6246763, at *4 (D. Del. Oct. 25, 2016) (alleging defendant's commercially available smartphones infringed plaintiff's patents on information and belief).

Noratech argues that *Belcher*'s applicability is limited because the Court based its opinion on the statutory framework of the Hatch-Waxman Act. (D.I. 44 at 2–5). While the Court in *Belcher* does focus on the language and purpose of the Act, nothing in *Belcher* prohibits application of a relaxed pleading standard in other similar situations. *Belcher*, 379 F. Supp. 3d at 331. The Court's rationale in *Belcher* is not idiosyncratic—lower pleading standards have regularly been adopted where "essential information lies uniquely within another party's control." *Exergen*, 575 F.3d at 1330–31; *McDermott*, 649 F. App'x at 267–68; *see also In re Burlington*, 114 F.3d at 1418. I find ANDA infringement suits outside the Hatch-Waxman Act to be such a situation and choose to apply the relaxed standard from *Belcher* here.

Novartis's complaint alleges that Noratech and MSN committed acts of infringement by filing their ANDAs, and that the challenged drug products will infringe one or more claims of its '918 patent. (D.I. 1 at 29–35, 72–75). These allegations are sufficient to meet the relaxed pleading standard of *Belcher*. *See* 379 F. Supp. 3d at 332 ("Plaintiff's allegations that Defendant committed an artificial act of infringement by filing its paper NDA, and that Defendant's proposed drug product will infringe Claims 6 and 7 of the '197 patent (an Orange Book-listed patent), are sufficient to survive Defendant's motion to dismiss."). The protective order prevents Novartis from asserting much more in its complaint than it did already, and it appears

unreasonable "to expect a plaintiff in such a position to develop the level of specificity [defendants] asks the Court to impose." *Belcher*, 379 F. Supp. 3d at 331.

B. Non-infringement as a matter of law

MSN argues that its ANDA product cannot infringe the '918 patent as a matter of law because the '918 patent claims an "amorphous" form of the compound while MSN's ANDA requires a crystalline form. (D.I. 66 at 6–7). At this stage, I lack sufficient information to adjudicate the issue of infringement. As Novartis has pled sufficient facts to plausibly suggest MSN's ANDA product infringes the '918 patent, its claim survives the Rule 12(c) motion.

As a preliminary matter, I agree with MSN that I can look at the ANDA in deciding this motion. This Court has found that, where such filings provide the basis for the complaint, ANDA or NDA filings are "integral" to the pleadings and can be relied upon in deciding a motion for judgment on the pleadings. *See Eagle Pharma., Inc. v. Slayback Pharma LLC*, 382 F. Supp. 3d 341, 343 n.1 (D. Del. 2019); *In re Bendamustine Consol. Cases*, 2015 WL 1951399, at *1 (D. Del. Apr. 29, 2015); *but see Par Pharma., Inc. v. Hospira Inc.*, 2018 WL 3343238, at *3 (D. Del. May 11, 2018). Here, where Novartis's infringement claims are primarily based on defendants' ANDA products, the ANDAs are integral to the complaint. (D.I. 1 at 19–21, 31–35).

I nevertheless do not have sufficient information to decide the broader question of infringement at this stage of the litigation. "[A]n infringement adjudication cannot be completed merely by reviewing the ANDA, and without taking into account any other evidence–including, most notably, expert testimony." *Par Pharma.*, 2018 WL 3343238, at *3; *cf. Eagle Pharma.*, 382 F. Supp. 3d at 344 (looking at the sole issue of whether plaintiff's doctrine-of-equivalents arguments are barred by the disclosure-dedication rule); *In re Bendamustine*, 2015 WL 1951399, at *1 (same). As an ANDA does not provide a complete answer to infringement, submitting an

ANDA does not, by itself, defeat infringement allegations. Viewed in the light most favorable to the non-moving party, Novartis's pleadings plausibly give rise to an infringement claim based on the identified patent and ANDA products. For example, as Novartis argues (D.I. 70 at 6–7), MSN's ANDA products may contain an amount of infringing material sufficient to raise an infringement theory under *SmithKline Beecham Corp. v. Apotex Corp*, 403 F.3d 1331, 1341 (Fed. Cir. 2005).[3] As I believe further fact discovery, expert testimony, trial, and briefing are likely all necessary to adjudicate the infringement allegations, I cannot grant a judgment on the pleadings of non-infringement.

IV. CONCLUSION

For the foregoing reasons, Noratech's motion to dismiss and MSN's motion for judgment on the pleadings are DENIED. An appropriate order will issue.

[3] As I must ignore evidence outside the pleadings, I do not credit the preliminary expert testing Novartis claims it conducted after the Complaint was filed. (D.I. 70 at 7). The theory Novartis presents nevertheless helps demonstrate the plausibility of an infringement claim.